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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,878	03/05/2002	Terry G. Kelley	COCH-0010	6957
7590 11/16/2005			EXAMINER	
JEFFREY J. KING, ESQ. GRAYBEAL JACKSON HALEY LLP 155-108TH AVENUE, N.E. SUITE 350 BELLEVUE, WA 98004-5901			BOGART, MICHAEL G	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/091,878

Applicant(s)

KELLEY, TERRY G.

Examiner

Michael G. Bogart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13, 16, 17, 22, 25, 26, 31 and 32 are rejected under 35 U.S.C. § 102(b) as being anticipated by Meckelburg (US 3,154,070).

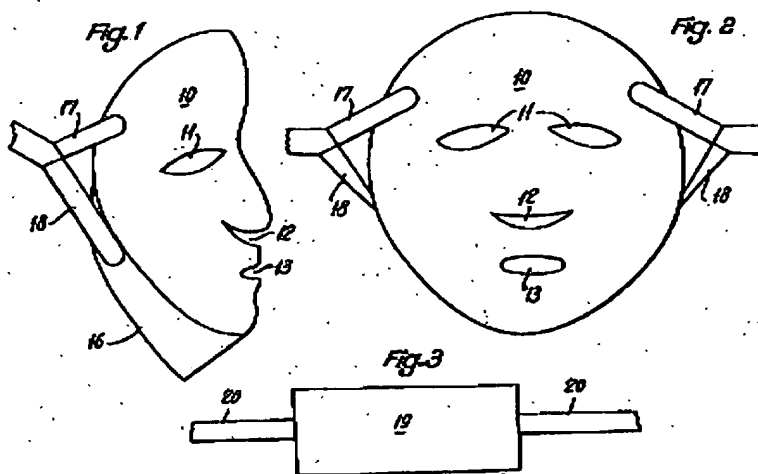
Regarding claim 1, Meckelburg teaches a facial or neck patch or mask for treatment of facial or neck skin aging in a mammalian subject comprising:

a flexible patch or mask body (10, 19) formed of a porous material (col. 2, lines 8-21), said patch or mask body (10, 19) sized and dimensioned to conform to a facial or neck skin area of said subject and having an undersurface adapted for effective delivery of an anti-aging compound;

attachment means (17, 18, 20) connected to the patch or mask body (10, 19) for securely, removably attaching the patch or mask (10, 19) in contact with one or more contoured facial and/or neck skin areas of the subject; at least one anti-aging effective compound (col. 1, lines 21-25; col. 4, lines 19-23) provided in chemical communication with an undersurface of the patch or mask body (10, 19) to effectuate delivery of the anti-aging compound to the contoured facial and/or neck skin area in an effective amount, and for an effective period of time to prevent

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or alleviate symptoms of skin aging in the facial and/or neck skin area to which the patch or mask is applied (see figures 1-3, below)(col. 1, lines 21-25; col. 2, lines 19-40).



Regarding claim 2, Meckelberg teaches a facial or neck patch or mask wherein the flexible patch or mask body (10, 19) is sized and dimensioned to conform to one or more contoured facial and/or neck skin area(s) of the subject selected from an orbital margin, nasal skin area, labial margin, mandibular, maxillary, or temporal lateral facial skin area, chin, jawl and/or neck skin area of the subject (see figures 1-3).

Regarding claim 3, Meckelberg teaches a facial or neck patch or mask wherein the facial or neck patch or mask conforms and stretches in conjunction with normal facial and neck skin movements as occur during jaw flexure, head turning, and eye opening and closure (col. 2, lines 17-40, discusses elastic construction of the device).

Regarding claim 4, Meckelberg teaches a patch or mask body (10, 19) constructed for expansion and/or elastic flexure in all directions planar to an undersurface of the patch or mask that is applied to a facial or neck skin area to be treated (col. 2, lines 17-40).

Regarding claim 5, Meckelberg teaches attachment means (17, 18, 20) selected from: a tie, elastic or other manual closure means that attaches to opposing lateral margins of the patch or mask (10, 19) and encircles a head of the subject.

Regarding claim 6, Meckelberg teaches a facial or neck patch comprising an orbital patch or mask (10, 11) sized and dimensioned to conform to an orbital margin of the subject for treatment of periorbital skin aging in the subject (see figures 1 & 2).

Regarding claim 7, Meckelberg teaches a orbital patch or mask (10) which conforms (11) to one or more portions of the orbital margin of the subject selected from a supraorbital margin, infraorbital margin, lateral orbital and/or medial orbital margin of the eye (see figures 1 & 2).

Regarding claim 8, Meckelberg teaches a patch or mask (10) comprising one or more separate or conjoined, contoured sections (11) individually shaped and dimensioned to conform to a selected portion of the orbital margin (see figures 1 & 2).

Regarding claim 9, Meckelberg teaches a orbital patch or mask (10) wherein said one or more separate or conjoined, contoured sections (11) are individually shaped and dimensioned to conform to a portion of the orbital margin selected from: a lenticular area of the supraorbital margin; a lenticular area of the infraorbital margin; a medial orbital margin; and a lateral orbital margin (see figures 1 & 2).

Regarding claim 10, Meckelberg teaches one or more separate or conjoined, contoured sections (11) are conjoined in a single patch or mask (10) having a unitary body or by interconnecting member(s) joining the individual sections in an anatomically integrated array of sections (see figures 1 & 2).

Regarding claim 11, Meckelberg teaches a facial or neck patch or mask (10) comprising a nasal skin patch or mask sized and dimensioned to conform (12) to a nasal skin surface of the subject for treatment or prevention of nasal skin aging in the subject (see figures 1 & 2).

Regarding claim 12, Meckelberg teaches a facial or neck patch or mask (10) comprising a labial skin patch or mask sized and dimensioned to conform (12) to a labial margin of the subject for treatment or prevention of perilabial skin aging in the subject (see figures 1 & 2).

Regarding claim 13, Meckelberg teaches a facial or neck patch or mask (19) comprising a neck skin patch or mask sized and dimensioned to conform to a neck skin surface of the subject for treatment or prevention of neck skin aging in the subject (see figure 3).

Regarding claim 16, Meckelberg teaches the facial or neck patch or mask (10, 19) wherein the patch or mask body, or at least an undersurface portion thereof, serves as a substrate or reservoir for receiving and retaining the anti-aging effective compound (col. 2, lines 17-40).

Regarding claim 17, Meckelberg teaches a the facial or neck patch or mask (10, 19) wherein the anti-aging effective compound is absorbed, adsorbed, or otherwise admixed with or invested in a material of the patch or mask body in direct chemical communication between the patch or mask body and the undersurface thereof through pores, fissures, perforations, and/or other communication channels provided within the patch or mask body (10, 19) or a layer thereof adjacent the undersurface (col. 2, lines 17-40).

Regarding claim 22, Meckelberg teaches a plurality of anti-aging effective compounds are applied simultaneously or coordinately with the patch or mask to yield enhanced treatment or prophylaxis of skin aging in the subject (col. 3, lines 19-23).

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Regarding claim 25, Meckelberg teaches a facial or neck patch or mask (10, 19) comprising a facial mask (10) shaped and dimensioned to conform to multiple facial skin areas (see figures 1 & 2).

Regarding claim 26, Meckelberg teaches a facial mask further comprising a separate or integral, self-contained or externally charged thermal element (column 1, lines 57-60).

Regarding claim 31, Meckelberg teaches a patch or mask body (10, 19) comprised of a polymer or fiber material (col. 2, lines 7-40).

Regarding claim 32, Meckelberg teaches a method for treating facial and/or neck skin aging in a mammalian subject comprising: applying a facial or neck patch or mask (10, 19) to a facial and/or neck skin area(s) in the subject and having an undersurface adapted for effective delivery of an anti-aging compound; and wherein the patch or mask comprises a flexible patch body formed of a porous material sized and dimensioned to conform to one or more contoured facial and/or neck skin area(s) of the subject; and removably securing the patch or mask (10, 19) to the facial and/or neck skin area(s) by attachment means (17, 18, 20) connected to the patch body (10, 19), wherein the patch or mask (10, 19) delivers an anti-aging effective compound to the facial skin and/or neck skin area(s) from an undersurface of the patch or mask body after the patch or mask has been applied to yield enhanced delivery and bioavailability of the anti-aging compound to underlying facial and/or neck skin area(s) to substantially prevent or alleviate one or more symptoms of facial and/or neck skin aging therein (claim 1).

Claims 1 and 27-30 are rejected under 35 U.S.C. § 102(b) as being anticipated by De St. Cyr (US 2,210,618).

Regarding claim 1, De St. Cyr teaches a facial or neck patch or mask for treatment of facial or neck skin aging in a mammalian subject comprising:

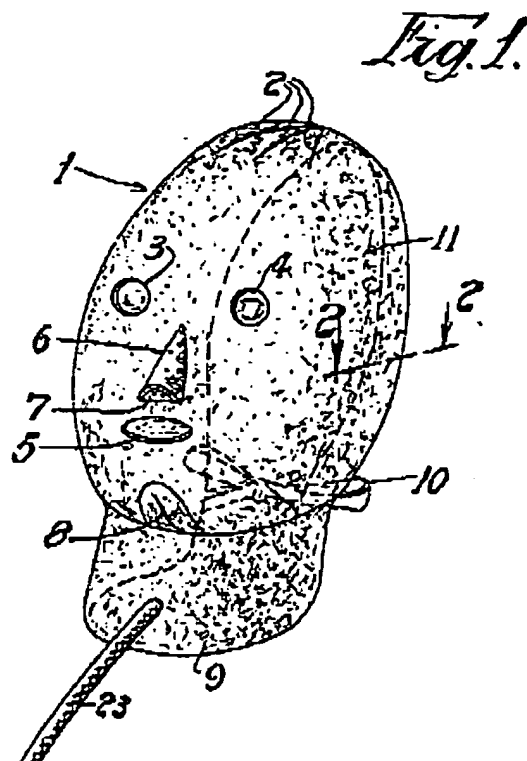
a flexible patch or mask body (1) formed of a porous material (11), said patch body (1) sized and dimensioned to conform to a facial or neck skin area of said subject and having an undersurface adapted for effective delivery of an anti-aging compound;

attachment means (10) connected to the patch or mask body (1) for securely, removably attaching the patch or mask (1) in contact with one or more contoured facial and/or neck skin areas of the subject; at least one anti-aging effective compound (heated paraffin wax) provided in chemical communication with an undersurface of the patch or mask body (1) to effectuate delivery of the anti-aging compound to the contoured facial and/or neck skin area in an effective amount, and for an effective period of time to prevent or alleviate symptoms of skin aging in the facial and/or neck skin area to which the patch or mask (1) is applied (see Fig. 1, below).

Regarding claim 27, De St. Cyr teaches a facial or neck patch or mask (1) wherein the thermal element is a heating element (col. 2, lines 29-44) to facilitate delivery and activity of the anti-aging effective compound by increasing the temperature at a target skin area.

Regarding claim 28, De St. Cyr teaches a facial or neck patch or mask wherein the thermal element is a thermal gel (melted wax) that can function as a heating and/or cooling element.

Regarding claim 29, De St. Cyr teaches a facial or neck patch or mask of claim wherein the thermal element is permanently or removably enclosed within a pocket or cavity attached to or surrounded by the patch or mask body (col. 2, lines 29-44).



Regarding claim 30, De St. Cyr teaches a facial or neck patch or mask of wherein the anti-aging effective compound (wax) is formulated with a polymeric delivery vehicle, hydrogel, or biodegradable polymer or matrix.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14, 15 and 24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Meckelberg as applied to claims 1-13, 16, 17, 22, 25, 26, 31 and 32 above, and further in view of Korol (US 4,747,845).

Meckelberg expressly teaches the claimed invention except for delayed release of the compound.

Korol teaches a synthetic resin matrix for extended release of medicaments which can be applied via an external skin dressing (abstract, figure 1).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to add the drug release mechanism of Korol to the mask or patch of Meckelberg in order to provide a means of controlling the release rate of its active compounds.

Regarding claim 15, Meckelberg teaches a facial or neck patch or mask of claim wherein the patch or mask effectively delivers the anti aging effective compound to achieve an effective concentration anti aging effective compound to reduce or prevent symptoms of facial and/or neck skin aging caused by degeneration of the microvascular system (col. 2, lines 38-40).

Regarding claim 24, any time released compound provided by the combination of Meckelberg and Korol would provide controlled, time-release delivery of one or more compound(s) for a prolonged delivery time period selected from: 1-4 hours; 4-8 hours; or more than 8 hours.

Claims 18 and 19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Meckelberg as applied to claims 1-13, 16, 17, 22, 25, 26, 31 and 32 above, and further in view of Lorenz (US 5,306,504 A).

Meckelberg teaches the claimed invention except for a bioadhesive.

Lorenze teaches a skin adhesive hydrogel (abstract).

At the time of the invention, it would have been obvious to combine the skin adhesive of Lorenze with the mask or patch of Meckelberg in order to provide a means of better securing the mask or patch to a patient while minimizing skin irritation.

Claims 20, 21 and 23 and 33-37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Meckelberg as applied to claims 1-13, 16, 17, 22, 25, 26, 31 and 32 above, and further in view of Kaddurah-Daouk (US 6,242,491 B1).

Meckelberg teaches the claimed invention except for the specific anti-aging compound.

Kaddurah-Daouk teaches the use of Coenzyme Q₁₀ or vitamin E as an anti-aging agent (col. 15, lines 7-11).

At the time of the invention, it would have been obvious to select Coenzyme Q₁₀ or vitamin E as the anti aging agent for the mask or patch of Meckelberg in order to provide an effective skin preserving effect.

Response to Arguments

Applicant's arguments filed 23 September 2005 have been fully considered but they are not persuasive.

Applicant asserts that neither Meckelburg nor De St Cyr disclose a mask having an undersurface adapted for effective delivery of an anti-aging compound. This argument is not persuasive because the referenced masks are shaped to fit over a human face. The referenced masks are designed to be a delivery device for oxygen, water, parafin wax and other anti-aging substances (for example, the honey-combed structure of Meckelburg holds water in place against

the facial skin; after wax is applied to the underside of the mask of De St Cyr, the mask is placed on a human face and the wax is transferred or delivered to the facial skin). These substances are delivered via the underside of the respective masks which actually contacts the facial skin when in use. Applicants do not positively claim any patch or mask structure which defines the undersurface in a manner which is materially different from that of the reference.

Applicants further assert that the disclosed masks fail to teach an "anti-aging effective compound", and that the reference merely teaches compounds for merely cosmetically altering the appearance of skin. This argument is not persuasive because the referenced masks disclose compounds, including parafin wax, water and oxygen do alleviate some of the symptoms of aging, such as wrinkling, dead skin cells, dry skin, oily build up, etc. Dry skin is another symptom of ageing that both references expressly indicate may be alleviated by their disclosed hydrating properties. Furthermore, giving the limitation "anti-aging effective compound" its broadest reasonable interpretation, the limitation is anticipated by a teaching of materials which alleviate superficial symptoms of aging, including appearance and dryness. Applicants have not claimed any compounds which do more than this, as they can not physically make the skin any younger than it is nor can they stop it from further aging, they can only alleviate past damage from aging and resist damage from future aging.

Applicants further assert that the referenced disclosures do not deliver its disclosed compounds in an effective amount. This argument is not persuasive because the referenced mask will continue to deliver its compounds to a face until it is either removed or all of the compound has leached out. Applicants also do not claim what an effective amount is in terms of actual amount or degree of anti-aging.

In response to applicant's argument that neither Korol nor Lorenz provide an anti-aging effective compound, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (571) 272-4933.

In the event the examiner is not available, the Examiner's supervisor, Tatyana Zalukaeva may be reached at phone number (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300 for formal communications. For informal communications, the direct fax to the Examiner is (571) 273-4933.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-3700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read "M. Bogart", with a long horizontal stroke extending to the right.

Michael Bogart
10 November 2005

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read "Tatyana", written in a cursive style.